03/11/2019

AurobindoPharma USA, Inc. Initiates a Voluntary Nationwide Consumer Level Recall Expansion of 39 Lots of Amlodipine Valsartan Tablets USP and Valsartan Tablets, USP due to the detection of NDEA (N-Nitrosodiethylamine) Impurity.

AurobindoPharma USA, Inc. contact 1-866-850-2876 Option 2

Recall being handled by:

Inmar\CLS-Medturn contact 1-877-208-2407

Acetris returns partner contact 888-280-2043

FOR IMMEDIATE RELEASE: 03/01/19: AurobindoPharma USA, Inc. and Acetris Health LLC. Are conducting a voluntary recall expansion of 39 lots of Valsartan and Amlodipine and Valsartan tablets to the consumer level due to the detection of trace amounts of an unexpected impurity found in the finished drug product. This recall is an expansion of the recall initiated 12/31/18 The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification. The expansion relates to lots distributed under the labels for AurobindoPharma USA, Inc. and Acetris Health, LLC. To date, AurobindoPharma USA, Inc. has not received any reports of adverse events related to this recall.

Amlodipine Valsartan Tablets USP and Valsartan Tablets USP are indicated to control high blood pressure and for the treatment of heart failure. Patients who prescribed Amlodipine Valsartan Tablets USP and Valsartan Tablets USP should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

NDC	Name and strength	Count	Lot number	Expiry
ACETRIS LOTS				
52343-122-30	Valsartan Tablets USP 40mg	30	470170038A	19-Oct
52343-122-30	Valsartan Tablets USP 40mg	30	470180010A	20-Feb
52343-122-30	Valsartan Tablets USP 40mg	30	470180012A	20-Mar
52343-123-90	Valsartan Tablets USP 80mg	90	471170019A	19-Oct
52343-123-90	Valsartan Tablets USP 80mg	90	471180006A	20-Mar

52343-123-90	Valsartan Tablets USP 80mg	90	471180007A	20-Mar
52343-123-90	Valsartan Tablets USP 80mg	90	471180016A	20-May
52343-124-90	Valsartan Tablets USP 160mg	90	472180005B	20-Feb
52343-124-90	Valsartan Tablets USP 160mg	90	472180011A	20-Apr
52343-124-90	Valsartan Tablets USP 160mg	90	472180012A	20-Apr
52343-125-90	Valsartan Tablets USP 320mg	90	473180007A	20-Mar
52343-125-90	Valsartan Tablets USP 320mg	90	473180008A	20-Mar
52343-125-90	Valsartan Tablets USP 320mg	90	473180011A	20-Apr
52343-125-90	Valsartan Tablets, USP 320mg	90	473180020B1	20-Jul
52343-125-90	Valsartan Tablets, USP 320mg	90	473170019B	19-Oct
AUROBINDO LOTS				
65862-570-30	Valsartan Tablets USP 40mg	30	470180008A	20-Feb
65862-570-30	Valsartan Tablets USP 40mg	30	470180014A	20-Mar
65862-570-30	Valsartan Tablets USP 40mg	30	470180016A	20-Mar
65862-571-90	Valsartan Tablets USP 80mg	90	471170015A	19-Sep
65862-571-90	Valsartan Tablets USP 80mg	90	471180004A	20-Feb
65862-571-90	Valsartan Tablets USP 80mg	90	471180005A	20-Feb
65862-572-90	Valsartan Tablets USP 160mg	90	472180001A	20-Jan
65862-572-90	Valsartan Tablets USP 160mg	90	472180002A	20-Jan
65862-572-90	Valsartan Tablets USP 160mg	90	472180003A	20-Jan
65862-572-90	Valsartan Tablets USP 160mg	90	472180004A	20-Jan
65862-572-90	Valsartan Tablets USP 160mg	90	472180007A	20-Mar
65862-572-90	Valsartan Tablets USP 160mg	90	472180008A	20-Mar
65862-572-90	Valsartan Tablets USP 160mg	90	472180009A	20-Mar
65862-572-90	Valsartan Tablets USP 160mg	90	472180010A	20-Mar
65862-572-90	Valsartan Tablets USP 160mg	90	472180013A	20-Apr
65862-572-90	Valsartan Tablets USP 160mg	90	472180014A	20-Apr
65862-573-90	Valsartan Tablets USP 320mg	90	473180004A	20-Feb
65862-573-90	Valsartan Tablets USP 320mg	90	473180005A	20-Feb
65862-573-90	Valsartan Tablets USP 320mg	90	473180006A	20-Mar
65862-573-90	Valsartan Tablets USP 320mg	90	473180017A	20-May

65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA17007-A	19-Oct
65862-570-30	Valsartan Tablets, USP 40mg	30	470180032A	20-May
65862-573-90	Valsartan Tablets, USP 320mg	90	473170019A	19-Oct
65862-573-90	Valsartan Tablets, USP 320mg	90	473180016A	20-May

Amlodipine Valsartan Tablets USP and Valsartan Tablets USP were distributed nationwide to AurobindoPharma USA, Inc. and Aceteris Health LLC wholesale, distributor, repackager and retail customers. AurobindoPharma USA, Inc. is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. AurobindoPharma USA, Inc. is arranging for return of all recalled products to Inmar. Instructions for returning recalled products are given in the recall letter.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact AurobindoPharma USA, Inc. at:

- 1-866-850-2876 Option 2
- pvg@aurobindousa.com
- Acetris returns partner 888-280-2043

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general **questions regarding the return of this product** please contact Inmar\CLS-Medturn at 1-877-208-2407 or email aurobindorecalls@inmar.com (live calls received 9 am -5:00 pm Eastern Time).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm Call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

AUROBINDO
Committed to healthier life!
www.AurobindoUSA.com

Each film-coated tablet contains: Valsartan USP 40 mg.

30 Tablets

NDC 52343-122-30

Distributed by:
Acetris Health, LLC
Saddle Brook, NJ 07663

Manufactured by:
Aurolife Pharma LLC
Dayton, NJ 08810

Issued: 12/2017

Usual Dosage: See package insert.

Valsartan Tablets, USP

40 mg

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

Rx only

Acetris

LM-2466

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N 52343122308

Each film-coated tablet contains: Valsartan USP 80 mg.

90 Tablets

NDC 52343-123-90

Distributed by:
Acetris Health, LLC
Saddle Brook, NJ 07663

Manufactured by:
Aurolife Pharma LLC
Dayton, NJ 08810

Issued: 12/2017

Usual Dosage: See package insert.

Valsartan Tablets, USP

80 mg

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

Rx only

Acetris

LM-2467

*

N 52343123909

Each film-coated tablet contains: Valsartan USP 160 mg.

90 Tablets

NDC 52343-124-90

Distributed by:
Acetris Health, LLC
Saddle Brook, NJ 07663

Manufactured by:
Aurolife Pharma LLC
Dayton, NJ 08810

Issued: 12/2017

Usual Dosage: See package insert.

Valsartan Tablets, USP

160 mg

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

Rx only

Acetris

LM-2468

*

N 52343124906

AUROBINDO
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Each film-coated tablet contains:
Valsartan USP 320 mg.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

90 Tablets NDC 52343-125-90

Valsartan Tablets, USP
320 mg

Rx only

Acetris

Distributed by:
Acetris Health, LLC
Saddle Brook, NJ 07663

Manufactured by:
Aurolife Pharma LLC
Dayton, NJ 08810

Issued: 12/2017

LM-2469

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N 52343125903

NDC 65862-570-30

Rx only

Valsartan Tablets USP
40 mg

AUROBINDO

30 Tablets

Each film-coated tablet contains:
Valsartan USP 40 mg.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

P1420824

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N 365862570307

*Over Printing Zone

Coding Area
(45 x 15 mm)
Dotted lines not to be printed

NDC 65862-571-90

Rx only

Valsartan Tablets USP
80 mg

AUROBINDO

90 Tablets

Each film-coated tablet contains:
Valsartan USP 80 mg.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

P1420826

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N 365862571908

*Over Printing Zone

Coding Area
(45 x 15 mm)
Dotted lines not to be printed

AUROBINDO
Committed to healthier life!
www.AurobindoUSA.com

NDC 65862-572-90

Rx only

Valsartan Tablets USP
160 mg

AUROBINDO **90 Tablets**

Each film-coated tablet contains: Valsartan USP 160 mg.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

N365862572905

P1420828

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*Over Printing Zone

Coding Area
(45 x 20 mm)
Dotted lines not to be printed

NDC 65862-573-90

Rx only

Valsartan Tablets USP
320 mg

AUROBINDO **90 Tablets**

Each film-coated tablet contains: Valsartan USP 320 mg.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

Dispense in tight container (USP).

Keep this and all drugs out of the reach of children.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

N365862573902

P1420830

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*Over Printing Zone

Coding Area
(45 x 20 mm)
Dotted lines not to be printed

NDC 65862-739-30

Rx only

Amlodipine and Valsartan Tablets USP
10 mg/160 mg

AUROBINDO **30 Tablets**

Each film-coated tablet contains 13.9 mg of amlodipine besylate USP equivalent to 10 mg amlodipine and valsartan USP 160 mg.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. **Protect from moisture.**

Keep this and all drugs out of the reach of children.

USP Organic Impurities Test pending.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India
Code: TS/DRUGS/22/2009

N365862739308

P1421830

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*Over printing Zone

Coding Area
(45 x 15 mm)
Dotted lines not to be printed